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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,864	06/28/2001	Keiichi Yokoyama	209524US0 CONT	3226

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EXAMINER	
PATTERSON, CHARLES L JR	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,864	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,41-43,72,73 and 75-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,14,18,19,21-38,41-43,72,73 and 75-86* is/are rejected.

7)☒ Claim(s) *11,12,15-17 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/03 has been entered.

In a review of the instant application, the examiner noted that he failed to initial reference AW in the PTO-1449 considered 1/23/04. This has now been initialed and is being sent with this action. The instant specification has been re-read and the instant claims re-considered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38, 41, 42, 72-73, 75, 79-84 and 86 are rejected under 35 U.S.C. 102(e) as being anticipated by Yokoyama, et al. (AA). The instant reference teaches a microbial transglutaminase that is dissolved in 8 M urea at pH 5.5 and then diluted to a concentration of 0.5 M urea and 50 mM phosphate duffer. The activity of this transglutaminase preparation is taught to be "about 30 U/mg...equal to the specific activity of natural" transglutaminase (column 12, lines 50-67). This is essentially the process used in the instant application to produce an "intermediate state" in the instant application and it is maintained that the other requirements of claim 75 are met, absent very convincing proof to the contrary. The use of transglutaminase to produce food and toiletries ("gelled cosmetics") is taught in column 1, lines 16-25.

Claims 38, 41-43, 72-73, 75, 79-84 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama, et al. (AA). The reference is characterized *supra*. It would have been obvious to have the transglutaminase at 2 mg/ml as taught in column 12, line 53, instead of in the range of 10-100 mg/ml of the instant claim. 2 mg/ml is not far below 10 mg/ml, and if the instant process would work within the range of 10-100 mg/ml, one of ordinary skill in the art would expect that it would also work at 2 mg/ml, absent unexpected results.

Claims 1-10, 13-14, 18, 19, 21-38, 41-43 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ejima, et al. (AY). This rejection is repeated for the reasons given in the last action. Applicants argu-

ments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the instant reference teaches in column 1, page 303 that "the native conformation of hIL-6 was obtained by rapidly removing the denaturant from the oxidized hIL6 solution without any dilution". The examiner has examined column 1 and the surrounding columns of the reference and has been unable to find this quotation. This fact was stated in the Advisory mailed 1/16/03, to which no reply to which has been received. Applicants then state that they "wonder how in the face of such contradictory teachings one of skill in the art would expect *any* results based on Ejima et al...[and that] the skilled artisan would likely dismiss the disclosure of Ejima et al as [*sic*, not] having any reasonable applicability to hIL-6, much less any other enzyme" (referring to the alleged quotation and the quotation concerning dilution on page 302). The examiner cannot reasonably reply to these allegations as the recitation on page 303 has not been found.

Applicants then argue that the purification of hIL-6 is taught by the reference, that this is not a transglutaminase as in the instant claims and to use the method taught here to purify transglutaminase would at best have been "obvious to try". It is argued that this cannot be the basis for obviousness. The examiner does not agree. Both transglutaminase and hIL-6 are biologically active proteins and one of ordinary skill in the art would believe that there would have been at least a reasonable expectation of success that the method taught by the instant reference could have been used to purify transglutaminase. This is the standard set forth by *In re O'Farrell*. This is especially true in view of the wide range of conditions in the instant claims such as "acidic", "neutral" and "about 5-fold to about 400-fold" in the instant claims. It is noted that claims 11, 12, 15-17 and 20, drawn

to conditions not taught in the instant reference, are not rejected under either 35 USC § 102 or 103.

Claims 1-10, 13-14, 18, 19, 21-38, 41-43, 72-73, 76-83 and 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ejima, et al. (AY) in view of Yokoyama, et al. (AA). The primary reference is characterized *supra*. The use of transglutaminase to produce food and toiletries ("gelled cosmetics") is taught in column 1, lines 16-25 of Yokoyama, et al. It would have been obvious to one of ordinary skill in the art to purify transglutaminase by the method taught by Ejima, et al. and to use is as a food or toiletry, as taught by Yokayama, et al.

Claims 11, 12, 15-17 and 20 are objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 5, 2004